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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,543	03/29/2004	Erning Xia	P03459	3425
23702	7590	11/06/2008		
Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER	
			PACKARD, BENJAMIN J	
			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			11/06/2008 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/812,543

**Applicant(s)**

XIA ET AL.

**Examiner**

Benjamin Packard

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2008 and 19 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 6-8, 13, 25-27, 29, 35-37, 40-44 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) 1, 6-8, 13 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29, 35-37, 40-44 and 79-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 08/04/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

**Claims 29, 35-37, 40-44, and 79-83** were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention where the claims use the phrase "organic, nitrogen-containing preservative agent."

This rejection is maintained.

Applicants assert the level of skill in the art is high, that specification when read as a whole provides sufficient guidance, and there is a relation between the partial structure and the function.

In response, the Examiner points out that the class of compounds which are organic and contain a nitrogen is extensive. While the class is limited by the ability to act as a preservative agent, there is no limitation that links the organic and nitrogen compound to the ability to function as a preservative. Examiner agrees that the level of skill in the art is high, but the specification appears to teach of only a very limited number of compounds, such as polyquaterniums and poly biguanides. Even the secondary reference cited by Applicants does not use the same phrase when describing

antimicrobials, but instead lists specific compounds with known microbial activity. It is the Examiner's position that while a small class of known antimicrobials are disclosed, they are not sufficient in numbers to be representative of the larger class of organic, nitrogen-containing preservative agents which are claimed.

**Claim 37** was also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention where the claim uses the trademarked term "Polymer JR".

This rejection is maintained and it appears no response was received with regards to this rejection in the comments with a file date of 08/04/2008 or 08/19/2008.

#### ***Claim Rejections - 35 USC § 103***

**Claims 29, 35-37, and 40-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cini et al (US 5,130,298) in view of Ellis et al (US 5,872,086).

Applicants discussed the range of zinc in the prior 102 rejection as being below the required amount and correctly pointed out that the list of preservatives did not contain a preservative which was an organic, nitrogen-containing preservative. With regards to the similar 103 rejection, Applicants assert there is no motivation to choose specific polymers where only the generic "polymer for adjusting viscosity" is taught.

Examiner is now modifying the original rejection to include claims 29 and 40-44 where it appears the range disclosed in Cini et al was miscalculated. Additionally, the rejection is converted to a 103 where the Examiner misconstrued the preservatives

disclosed in Cini et al and a secondary reference is now relied upon in rejection of that limitation.

Cini et al was previously discussed in the action dated 06/05/2008. Additional reasoning and responses to Applicants' comments are noted below.

Examiner first would like to note in reference to the Cini et al calculation on page 6 of Applicant's remarks dated 08/04/2008, that Applicant's calculation is based on the assumption that 10mM of zinc is used. Yet as previously stated, Cini et al suggests the range may include 5mM - 10mM of zinc. Therefore, where 10mM of zinc results in 0.065 wt%, it appears a dosage of 5 mM of zinc would result in half that value or 0.0325 wt%, which reads on the instantly claimed range.

Second, with regard to the desire to pick a specific polymer, *KSR* does not require an explicit statement of motivation to be obvious. Instead, one of ordinary skill in the art would find it obvious to choose a known polymer, such as disclosed in the secondary reference, that adjusts viscosity in ophthalmic compositions, as suggested in the primary reference, where both compositions have similar components, and the polymer is used for the very same purpose, to adjust the viscosity. *Sinclair & Carroll Co. v. Interchemical, Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Third, Ellis et al teaches preferred antimicrobial agents as preservatives, which include polyhexamethylene biguanide. As with the polymer selection, it would be obvious to one of ordinary skill in the art to substitute a known antimicrobial agent/preservative useful in similar composition into the generic class of preservatives of Cini et al.

Finally, it is assumed that Applicant's argument with regard to the motivation in Cini et al is intended to differentiate the instantly claimed composition from the teaching of Cini et al, it is noted that the claims are directed to a composition. Therefore, the motivation to combine the components is immaterial where resulting obviousness analysis makes the instantly claimed composition obvious for other reasons.

**Claims 79-80** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cini et al (US 5,130,298) in view of Bergamini et al (US 5,597,560).

Cini et al is discussed previously in the rejection dated 06/05/2008, which included the teaching of a buffer.

Cini et al does not disclose the buffers tris(hydroxymethyl)aminomethane (TRIS), amino alcohol and any one mixture thereof.

Bergamini et al teaches pharmaceutically acceptable eye solutions which are buffered using tris(hydroxymethyl)aminomethane (claim 86) where the pH range is intended to be between about pH 7.0 to pH 9.0.

Bergamini does not disclose the addition of zinc.

It would have been obvious to one of ordinary skill in the art to substitute a known buffer agent used previously in ophthalmic compositions for the buffer agent of the composition of Cini et al, where both share the same function. Sinclair & Carroll Co. v. Interchemical, Corp., 325 U.S. 327, 65 USPQ 297 (1945).

**Claims 81-83** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cini et al (US 5,130,298) in view of Asgharian (US 6,316,506).

Cini et al was discussed previously and above.

Cini et al does not disclose the addition of hydroxypropyl guar triammonium chloride.

Asgharian teaches the use of hydroxypropyl guar in ophthalmic solutions at a range of 0.1-1.0% w/v as a means of gelling, or changing the viscosity (claims 1, 5 and 6).

Asgharian does not teach the addition of zinc or the other components instantly claimed.

It would have been obvious to one of ordinary skill in the art to use a gelling agent used previously in ophthalmic compositions to modify the viscosity of the composition of Cini et al. Sinclair & Carroll Co. v. Interchemical, Corp., 325 U.S. 327, 65 USPQ 297 (1945).

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612